

Process and Information Required to Determine Eligibility of Drugs, Biologicals, and Radiopharmaceutical agents for Transitional Pass-Through Provisions Under the Hospital Outpatient Prospective Payment System (OPPS)

(Effective January 1, 2005)

Please note: For process and information required to apply for assignment and payment for **new technology service APCs or for additional device categories** go to the main OPPS web page, currently at <http://www.cms.hhs.gov/providers/hopps/apc.asp> or <http://cms.hhs.gov/medlearn/refopps/asp> to see the latest instructions.

This announcement describes in detail the process and information required for applications requesting transitional pass-through payment for drugs, biologicals, and radiopharmaceutical agents under the Medicare hospital outpatient prospective payment system (OPPS). These instructions apply solely to requests submitted on or after January 1, 2005 for transitional pass-through provisions for drugs, biologicals, and radiopharmaceuticals.

Because CMS intends to make information used in the rate setting process under the OPPS available to the public for analysis, applicants are advised that any information submitted, including commercial or financial data, is subject to disclosure for this purpose.

We will accept transitional pass-through applications for drugs, biologicals and radiopharmaceutical agents on an ongoing basis. However, we must receive applications sufficiently in advance of the first calendar quarter in which transitional pass-through status is sought to allow time for analysis, decision-making, and computer programming. The table below indicates the earliest date that pass-through status could be implemented once a completed application and all additional information are received.

CMS Must Have Complete Application and All Necessary Information by the first business date in	Earliest Date To Be Considered For Pass-Through Status Effective. . .
March	July 1
June	October 1
September	January 1
December	April 1

A longer evaluation period may be required if an application is incomplete or if further information is required upon which to base a determination of pass-through eligibility.

An application is not considered complete until—

- All required information has been submitted, AND
- All questions related to such information have been answered.

BACKGROUND:

Section 1833(t)(6) of the Act provides for temporary additional payments or “transitional pass-through payments” for certain drugs and biological agents. As originally enacted by the BBRA, this provision required the Secretary to make additional payments to hospitals for current orphan drugs, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act (Pub. L. 107-186); current drugs and biological agents and brachytherapy used for the treatment of cancer; and current radiopharmaceutical drugs and biological products. For those drugs and biological agents referred to as “current,” the

transitional pass-through payment began on the first date the hospital OPPS was implemented (before enactment of BIPA (Pub. L. 106-554), on December 21, 2000).

Transitional pass-through payments are also required for certain “new” drugs, devices and biological agents that were not being paid for as a hospital OPD service as of December 31, 1996, and whose cost is “not insignificant” in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years. Transitional pass-through payments for drugs and biologicals under the OPPS are discussed in the final rule published in the April 7, 2000 Federal Register (65 FR 18478), and in subsequent OPPS rules and issuances, which can be found at, <http://www.cms.hhs.gov/regulations/hopps/default.asp>, <http://www.cms.hhs.gov/medlearn/refopps.asp>, and <http://www.cms.hhs.gov/manuals/default.asp>.

Section 1833(t)(6)(D)(i) of the Act sets the payment rate for pass-through eligible drugs and biologicals (assuming that no pro rata reduction in pass-through payment is necessary) as the amount determined under section 1842(o) of the Act. Section 303(c) of Pub. L. 108-173 amended Title XVIII of the Act by adding new section 1847A. This new section establishes the use of the average sales price (ASP) methodology for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. Therefore, as we stated in the November 15, 2004 Federal Register (69 FR 65776), in CY 2005, we will pay under the OPPS for drugs and biologicals with pass-through status consistent with the provisions of section 1842(o) of the Act as amended by Pub. L. 108-173 at a rate that is equivalent to the payment these drugs and biologicals will receive in the physician office setting, and established in accordance with the methodology described in the CY 2005 Physician Fee Schedule final rule. Information on Average Sales Price is found at <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

REQUIRED INFORMATION:

The information in **items 1-10**, below, is required in **every application** for pass-through payment for a drug, biological or radiopharmaceutical. An application that does not include the following information is considered incomplete and cannot be acted upon:

1. The trade name and generic name of the product.
2. A detailed description of the clinical application of the product:
 - a. What it is and what it does.
 - b. The form in which it is supplied (i.e., solution, tablet, etc.).
 - c. Method of administration (intramuscularly, intravenously, orally, subcutaneously, sublingually, etc.).
 - d. Manner of packaging (indicate dosages/concentrations per ml, per tablet, per mCi, etc.).
 - e. The usual minimum dosage per day for one patient.
 - f. The usual maximum dosage per day for one patient.
 - g. The Healthcare Common Procedure Coding System (HCPCS) code(s), if any, used to identify the product. Specifically, which code(s) is/are used to report the use of this drug or biologic to third party payers? **(NOTE: APPROVAL OF A DRUG OR BIOLOGICAL FOR A TRANSITIONAL PASS-THROUGH PAYMENT UNDER THE OPPS IS NOT CONTINGENT ON PRIOR ASSIGNMENT OF A NATIONAL HCPCS CODE.)**
 - h. How dosages are measured.
3. A copy of the most recently published average wholesale price (AWP), including the date of publication and compendium where published.
4. Average Sales Price (ASP), or Wholesale Acquisition Cost (WAC).
5. The current cost of the drug or biological to hospitals, that is, the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind. In other words, submit the best and latest information available that provides evidence of the actual cost to hospitals for a specific drug or biological specified in terms of dosage and concentration.
6. The date of sale of first unit.
7. Usage (i.e., projected volume) by site of service (i.e., inpatient, outpatient, physician office, etc.).
8. A copy of the Food and Drug Administration (FDA) approval/clearance letter for the product.

9. A copy of the package insert.
 10. Name(s), address(es), e-mail addresses and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different from the requester, give the name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.
 11. Other information as CMS may require to evaluate a specific request or that the applicant believes CMS may need to evaluate the application.
- Note that a separate application is required for each distinct drug or biological included in a request. For example, if an applicant requests transitional pass-through status for five new drugs, the required information listed above must be completed for each of the five drugs.

WHERE TO SEND APPLICATIONS

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail. Mail six copies of each completed application to the following address:

OPPS Pass-Through Applications
Division of Outpatient Care
Mailstop C4-05-17
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Questions pertaining to the pass-through payment application process for drugs and biologicals may be sent via e-mail to the Division of Outpatient Care mailbox, OutpatientPPS@cms.hhs.gov, or by phone to 410-786-0387.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0802. The time required to complete this information collection is estimated to average 3.5 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

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